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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,446	03/26/2001	Virginia C. Gordon	SAFTY-001BC	2044

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/22/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,446

Applicant(s)

GORDON ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 67-78 is/are pending in the application.
- 4a) Of the above claim(s) 68-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 68-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 29 April 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 7.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed April 29, 2002 in Paper No. 8 is acknowledged. Claims 1, 4-5, 7, and 67 are amended. Claims 68-78 are added. Claims 1-7 and 67-78 are pending.

2. The rejection made under 35 U.S.C. § 103 for Claims 7 and 67 as patentable over Root et al. (US Patent 4,948,564) in view of Clarke et al. (US Patent 4,904,394) is in error. The rejection should be Root et al. (US Patent 4,948,564) in view of Sanadi (US Patent 5,342,581). The error was confirmed and clarified in a phone interview with Mr. Greg Holtrigel on April 15, 2002 (see attached interview summary).

Election/Restrictions

3. Newly submitted claims 68-78 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The pending claims (Claims 1-7, and 67-78) are group as follows:

- a. Group I is Claims 1-7 and 67 (original invention).
- b. Group II is Claims 68-77.
- c. Group III is Claim 78.

Inventions of Groups I, II and III are unrelated and independent inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions as claimed have different required components that have different modes of operation and functions.

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The feature of a differential pressure source to cause pressure differential between each of the sample receiving wells and each of the filtrate receiving vessels of Group I is not required by the claims of Group II and III. The feature of a cover that sealed over the cavity of the base and comprised of a sample port disposed over the filtrate receiving vessel of Group II is not required by the claims of Group I and III. The feature of a second membrane module nested in the membrane module disposed over the sample port of Group III is not required by the claims of Group I and II.

Because these inventions are distinct for the reasons given above and the searches required are not co-extensive thus requiring a burdensome search, restriction for examination purposes as indicated is proper. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group II would involve a determination of the patentability of the cover that sealed over the cavity of the base and comprised of a sample port disposed over the filtrate receiving vessel while a patentability determination for Group III would involve a consideration of the patentability of the second membrane module nested in the membrane module disposed over the sample port. These considerations are very different in nature.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 68-78 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. The requirement is deemed proper and is therefore made **Final**.

Drawings

5. The corrected or substitute drawings were received on April 29, 2002. These drawings are acceptable.

6. Applicant has indicated that formal drawings will be submitted upon indication of allowable subject matter. Applicant is reminded and advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. ***The requirement for corrected drawings will not be held in abeyance.***

7. The previous rejections made of record for claims 1-7 and 67 have been withdrawn in view of applicant's amendments of the claims such that the lid is for sealing each of the filtrate receiving vessels and cavity of the housing, and the lid having a sample port bounded by an edge extending from the surface of the lid away from the cavity. Therefore, the amended claims have now overcome the prior art of Root et al (US Patent 4,948,564). The following rejections are necessitated by the amended claims.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-7 and 67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended Claim 1 recites an apparatus that comprise of a housing, a filtrate-receiving vessel, a membrane, a sample-receiving well, a lid for sealing each of the filtrate receiving vessels and cavity of the housing and having a sample port bounded by an edge extending from the surface of the lid away from the cavity in which the edge is structure to retain the membrane, and a differential pressure source. Such a lid is not disclosed in the specification as originally filed.

The specification discloses four different apparatuses. The first apparatus comprise of a vacuum base, a test tube rack, a cover that is generally a flat member having a series of sample ports formed therein, membrane modules, and lids that are mountable in sealing contact on the rim of each primary membrane module and each lid has a limited air inflow port (pg. 13, lines 11-17; pg. 14, lines 1-2; pg. 16, lines 13-17; pg. 19, lines 8-12). The second apparatus comprise of a vacuum base, a filtrate receiving wells, plate-type membrane modules having multiple cavities with bottom opening that have membranes mounted transversely within, and a cover having individual air inlet ports formed therein (pg. 18, lines 27-30 to pg. 19, lines 1-3). The third apparatus comprise of a vacuum base, a receiving unit with a plurality of receiving wells, a support member having a plurality of apertures, plate-type membrane modules having multiple cavities

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with bottom opening that have membranes mounted transversely within, a sample receiving unit with a plurality of sample receiving wells, and a lid that have a plurality of limited air inlet openings is placed in sealing contact on top of the sample receiving unit (pg. 21, lines 22-30 to pg. 22, lines 1-3). The forth apparatus comprise of a base, a receiving unit with a plurality of receiving wells, a support member having a plurality of apertures, first and second membrane modules and a positive pressure lid (pg. 24, lines 16-19).

Nowhere in the specification is there a teaching of the device as claimed in Claim 1. The apparatuses disclosed in the specification require that the lid either be in sealing contact with the sample receiving unit or the membrane module. The specification does not teach a lid, i.e. one, for sealing each of the filtrate receiving vessels and the cavity of the housing.

In the event that applicant believes support for the amendment is available in the specification. It is respectfully requested that applicant point to the page and line number where such support maybe found.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-7 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The limitation of a lid that sealed each of the filtrate receiving vessels and cavity of the housing of Claim 1 is vague and indefinite because how it is possible for a lid to individually seal each filtrate receiving vessels and also the cavity of the housing?

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-2, 4-7 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. (US Patent 4,902,481).

Clark teaches a multiwell filtration apparatus for the assay of biological and biochemical materials (col. 1, lines 66-68; fig. 1). The multiwell filtration apparatus comprise of a base (housing having a cavity) (ref. #2 of fig. 1), a receiving plate (ref. #8 of fig. 1) having a plurality of individual chambers (ref. #9 of fig. 1) for collecting filtrate, a plate (ref. #13 of fig. 1-3) that house the membrane (ref. #30 of fig. 1) and positioned over each individual chamber of ref. #9 (col. 3, lines 5-25), a support (lid) (ref. #10 of fig. 1) that covers the receiving plate (ref. #8) and the base, and a filtration plate (ref. #12 of fig. 1) with individual well (ref. #11 of fig. 1), which has an opening (fig. 1 and 3) (col. 2, lines 53-68 to col. 3, lines 1-25; fig. 1-3). The base acts a vacuum chamber (col. 2, lines 56-59). The membrane can be bonded to the filtration plate (ref. #12) (col. 3, lines 26-28) that would form two portion of the membrane. The plate (ref. #13) is

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snap or press to fit filtration plate (ref #12) (col. 3, lines 17-18; fig. 3). The multiwell filtration apparatus of Clark anticipates the claimed apparatus.

Claim Rejections - 35 USC § 103

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Patent 4,902,481) in view of Oprandy (US Patent 5,039,493).

The multiwell filtration apparatus of Clark is disclosed above.

The apparatus of Clark differs from the claimed invention in failing to specifically teach a pressure source that provides a positive pressure.

Oprandy disclosed a positive pressure blotting apparatus with filtering means (col. 1, lines 65-68 to col. 2, lines 1-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the vacuum of Clark with a pressure source that provides a positive pressure as taught by Oprandy because positive and negative pressure sources are functionally equivalent means for achieving filtration of a sample. Specifically, Oprandy teaches that imposing a positive pressure on a filtration system provides the advantage of directly concentrating and forcing the sample through the membrane, achieving greater efficiency for the same power output as compare to a device such as a vacuum (col. 3, lines 15-21).

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

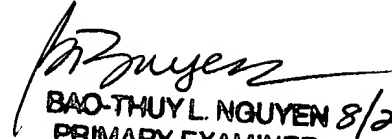
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct

August 20, 2002


BAO-THUY L. NGUYEN 8/21/02
PRIMARY EXAMINER